

INTERNATIONAL COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP12204	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU00/00125	International filing date (<i>day/month/year</i>) 23 February 2000	Priority Date (<i>day/month/year</i>) 23 February 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ G01N 33/48, 33/487.		
Applicant SYDNEY IVF PTY LTD et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.																								
2.	This REPORT consists of a total of 3 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 1 sheet(s).																								
3.	This report contains indications relating to the following items: <table style="width: 100%; border: none;"> <tr> <td style="width: 5%;">I</td> <td style="width: 5%;"><input checked="" type="checkbox"/></td> <td style="width: 90%;">Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td><input type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table>	I	<input checked="" type="checkbox"/>	Basis of the report	II	<input type="checkbox"/>	Priority	III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/>	Lack of unity of invention	V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input type="checkbox"/>	Certain documents cited	VII	<input type="checkbox"/>	Certain defects in the international application	VIII	<input type="checkbox"/>	Certain observations on the international application
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Date of submission of the demand 8 May 2000	Date of completion of the report 17 July 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer PHILIPPA WYRDEMAN Telephone No. (02) 6283 2554

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description, pages 1-34, as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☒ the claims, pages 35-38, as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 39, received on 11 July 2000 with the letter of 11 July 2000
- ☒ the drawings, pages 1/2-2/2 , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☒ the claims, Nos. 30-32
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-29	YES
	Claims None	NO
Inventive step (IS)	Claims 1-29	YES
	Claims None	NO
Industrial applicability (IA)	Claims 1-29	YES
	Claims None	NO

2. Citations and explanations (Rule 70.7)

None of the prior art teaches or fairly suggests a method of isolating a cytoplasmic fraction from an oocyte or an embryonic cell as claimed. Therefore, claims 1-29 are considered both novel and inventive.

The claimed subject matter is considered to have industrial applicability.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00125

A. CLASSIFICATION OF SUBJECT MATTER												
Int. Cl. 7: G01N 33/48, 33/487.												
According to International Patent Classification (IPC) or to both national classification and IPC												
B. FIELDS SEARCHED												
Minimum documentation searched (classification system followed by classification symbols) SEE ELECTRONIC DATABASE BOX BELOW												
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched SEE ELECTRONIC DATABASE BOX BELOW												
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Chem Abs, Medline, WPIDS Key words: cytoplasm, oocyte, ova, embryonic cell, viable, viability, function, fertility, development, biopsy, harm, injure, impair, damage Genebank, EMBL: Primers L820 and H1363												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X	METHA, A. B. et al (1989) "A new genetic polymorphism in the 16S ribosomal RNA gene of human mitochondrial DNA" <i>Ann. Hum. Genet.</i> Vol. 53, pages 303-310. See whole document	30-32										
A		1-29										
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input type="checkbox"/> See patent family annex												
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art											
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family											
"P" document published prior to the international filing date but later than the priority date claimed												
Date of the actual completion of the international search 23 March 2000		Date of mailing of the international search report 28 MAR 2000										
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer PHILIPPA WYRDEMAN Telephone No : (02) 6283 2554										

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00125

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Invention 1 is directed to a method of isolating a cytoplasmic fraction from an oocyte. The special technical feature of this invention resides in the removal of up to 5% of the volume of the oocyte.

Invention 2 is directed to methods of detecting a nucleotide sequence, polymorphism or mutation in a mitochondrial genome. The special technical feature of this invention resides in the use of an oligonucleotide in the method of detection

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing:

31 August 2000 (31.08.00)

International application No.:

PCT/AU00/00125

Applicant's or agent's file reference:

AS:FP12204

International filing date:

23 February 2000 (23.02.00)

Priority date:

23 February 1999 (23.02.99)

Applicant:

JANSEN, Robert et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International preliminary Examining Authority on:

08 May 2000 (08.05.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 338.83.38

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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 24 JUL 2000

PCT

Applicant's or agent's file reference FP12204	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU00/00125	International filing date (<i>day/month/year</i>) 23 February 2000	Priority Date (<i>day/month/year</i>) 23 February 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ G01N 33/48, 33/487.		
Applicant SYDNEY IVF PTY LTD et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 3 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 1 sheet(s).
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 8 May 2000	Date of completion of the report 17 July 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer PHILIPPA WYRDEMAN Telephone No. (02) 6283 2554

I. Basis of the report

1. With regard to the **elements** of the international application:*
- ☐ the international application as originally filed.
- ☒ the description, pages **1-34**, as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☒ the claims, pages **35-38**, as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **39**, received on **11 July 2000** with the letter of **11 July 2000**
- ☒ the drawings, pages **1/2-2/2** , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of
2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☒ the claims, Nos. **30-32**
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-29	YES
	Claims None	NO
Inventive step (IS)	Claims 1-29	YES
	Claims None	NO
Industrial applicability (IA)	Claims 1-29	YES
	Claims None	NO

2. Citations and explanations (Rule 70.7)

None of the prior art teaches or fairly suggests a method of isolating a cytoplasmic fraction from an oocyte or an embryonic cell as claimed. Therefore, claims 1-29 are considered both novel and inventive.

The claimed subject matter is considered to have industrial applicability.

- 39 -

(a) isolating a cytoplasmic fraction which includes mitochondria from the embryonic cell according to the method of claim 16; and

5 (b) comparing the number of mitochondrial genomes in the fraction with a nucleotide sequence, polymorphism or mutation, with the number of genomes without the nucleotide sequence, polymorphism or mutation in the fraction.

10 28. A method according to claim 27 wherein the nucleotide sequence, polymorphism or mutation of the mitochondrial genome is one which causes, or is suspected of causing, or is associated with, a disease or dysfunction in the embryonic cell, or in progeny descended from the cell.

15 29. A method according to claim 28 wherein the nucleotide sequence, polymorphism or mutation is shown in Table 1.

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

GRIFFITH HACK
GPO Box 4164
SYDNEY NSW 2001

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing
(day/month/year) **19 May 2000**

Applicant's or agent's file reference
FP12204

REPLY DUE within **TWO MONTHS**
from the above date of mailing

International application No.

International filing date (day/month/year)

Priority Date (day/month/year)

PCT/AU00/00125

23 February 2000

23 February 1999

International Patent Classification (IPC) or both national classification and IPC

Int. Cl. ⁷ G01N 33/48, 33/487

Applicant

SYDNEY IVF PTY LTD et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- | | | |
|------|-------------------------------------|--|
| I | <input checked="" type="checkbox"/> | Basis of the opinion |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input checked="" type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

3. The applicant is hereby **invited to reply** to this opinion.

- When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).
- How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.
- Also** For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **23 June 2001**

Name and mailing address of the IPEA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized Officer

PHILIPPA WYRDEMAN
Telephone No. (02) 6283 2554

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

Invention 1 is directed to a method of isolating a cytoplasmic fraction from an oocyte. The special technical feature of this invention resides in the removal of up to 5% of the volume of the oocyte.

Invention 2 is directed to methods of detecting a nucleotide sequence, polymorphism or mutation in a mitochondrial genome. The special technical feature of this invention resides in the use of an oligonucleotide in the method of detection.

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

WRITTEN OPINION

International application No.

PCT/AU00/00125

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-29	YES
	Claims 30-32	NO
Inventive step (IS)	Claims 1-29	YES
	Claims 30-32	NO
Industrial applicability (IA)	Claims 1-32	YES
	Claims None	NO

2. Citations and explanations

The following citation is referred to:

D1. METHA, A. B. et al (1989) "A new genetic polymorphism in the 16S ribosomal RNA gene of human mitochondrial DNA" *Ann. Hum. Genet.* Vol. 53, pages 303-310

Novelty:

This document discloses oligonucleotides that are approximately 20bp in length directed to polymorphism in the 16S ribosomal RNA gene of human mitochondrial DNA. Whilst the document does not disclose a "kit" per se, the term "kit for use" is a descriptor that holds no limitation upon the use to which the things contained within said kit are put. Thus claims to a kit containing an oligonucleotide for use in various methods are merely claims to the oligonucleotide per se. Thus this citation is relevant to the question of novelty over claims 30-32.

Inventive Step:

Notwithstanding the above argument, claims 30-32 lack any inventive step in light of D1 because there is no invention in placing a known substance, in this case the oligonucleotide, in a kit form. No surprising or unexpected result is obtained by presenting a substance in a kit form and thus no inventive step can be acknowledged.

Industrial Applicability:

The claimed subject matter is considered industrially applicable.

REPLACED BY
WIT 34 A200T

- 39 -

(a) isolating a cytoplasmic fraction which includes mitochondria from the embryonic cell according to the method of claim 16; and

5 (b) comparing the number of mitochondrial genomes in the fraction with a nucleotide sequence, polymorphism or mutation, with the number of genomes without the nucleotide sequence, polymorphism or mutation in the fraction.

10 28. A method according to claim 27 wherein the nucleotide sequence, polymorphism or mutation of the mitochondrial genome is one which causes, or is suspected of causing, or is associated with, a disease or dysfunction in the embryonic cell, or in progeny descended from the cell.

15 29. A method according to claim 28 wherein the nucleotide sequence, polymorphism or mutation is shown in Table 1.

20 30. A kit for use in a method according to claim 9 or claim 12, the kit including an oligonucleotide which is capable of detecting a nucleotide sequence, polymorphism or mutation in a mitochondrial genome which causes, or is suspected of causing, or is associated with, a disease or dysfunction in an oocyte, or in progeny descended from a fertilized oocyte.

25 31. A kit for use in a method according to claim 24 or claim 27, the kit including an oligonucleotide which is capable of detecting a nucleotide sequence, polymorphism or mutation in a mitochondrial genome which causes, or is suspected of causing, or is associated with, a disease or
30 dysfunction in an embryonic cell, or in progeny descended from an embryonic cell.

- 40 -

32. A kit according to claim 30 or claim 31, wherein the oligonucleotide is capable of detecting a nucleotide sequence, polymorphism or mutation shown in Table 1.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : G01N 33/48, 33/487	A1	(11) International Publication Number: WO 00/50895 (43) International Publication Date: 31 August 2000 (31.08.00)
(21) International Application Number: PCT/AU00/00125 (22) International Filing Date: 23 February 2000 (23.02.00) (30) Priority Data: PP 8841 23 February 1999 (23.02.99) AU (71) Applicant (for all designated States except US): SYDNEY IVF PTY LTD [AU/AU]; 4 O'Connell Street, Sydney, NSW 2000 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): JANSEN, Robert [AU/AU]; 4 O'Connell Street, Sydney, NSW 2000 (AU). DE BOER, Kylie [AU/AU]; 4 O'Connell Street, Sydney, NSW 2000 (AU). (74) Agent: GRIFFITH HACK; G.P.O. Box 4164, Sydney, NSW 2001 (AU).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: ISOLATING A CYTOPLASMIC FRACTION WITHOUT IMPAIRING THE VIABILITY OF OOCYTES AND EMBRYONIC CELLS (57) Abstract A method of isolating a cytoplasmic fraction from an oocyte which does not impair the capacity of the oocyte to be fertilized, the method including the step of releasing a cytoplasmic fraction from the oocyte which is about 5 % of the volume of the oocyte. A method of isolating a cytoplasmic fraction from an embryonic cell which does not impair the developmental potential of the cell, the method including the step of releasing a cytoplasmic fraction from the cell which is about 5 % of the volume of the cell.		

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00125

A. CLASSIFICATION OF SUBJECT MATTER												
Int. Cl. 7: G01N 33/48, 33/487.												
According to International Patent Classification (IPC) or to both national classification and IPC												
B. FIELDS SEARCHED												
Minimum documentation searched (classification system followed by classification symbols) SEE ELECTRONIC DATABASE BOX BELOW												
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched SEE ELECTRONIC DATABASE BOX BELOW												
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Chem Abs, Medline, WPIDS Key words: cytoplasm, oocyte, ova, embryonic cell, viable, viability, function, fertility, development, biopsy, harm, injure, impair, damage Genebank, EMBL: Primers L820 and H1363												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X	METHA, A. B. et al (1989) "A new genetic polymorphism in the 16S ribosomal RNA gene of human mitochondrial DNA" <i>Ann. Hum. Genet.</i> Vol. 53, pages 303-310. See whole document	30-32										
A		1-29										
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input type="checkbox"/> See patent family annex												
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention											
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art											
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"P" document published prior to the international filing date but later than the priority date claimed												
Date of the actual completion of the international search 23 March 2000		Date of mailing of the international search report 28 MAR 2000										
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer PHILIPPA WYRDEMAN Telephone No : (02) 6283 2554										

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00125

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Invention 1 is directed to a method of isolating a cytoplasmic fraction from an oocyte. The special technical feature of this invention resides in the removal of up to 5% of the volume of the oocyte.

Invention 2 is directed to methods of detecting a nucleotide sequence, polymorphism or mutation in a mitochondrial genome. The special technical feature of this invention resides in the use of an oligonucleotide in the method of detection

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.